original **informal** drawings in Figure 3 as filed. For the Examiner's convenience a copy of the originally filed informal Figure 3 is attached herewith. The confusion arose, when the new **formal** drawings of Figures 1 through 3 were subsequently filed. In those formal drawings, the reference signs in question were inadvertently omitted from Figure 3. Therefore, Applicants are submitting concurrently herewith a set of corrected formal drawings. The reference signs 50, 52, 54a, 54b, and 56a are shown clearly in Figure 3, which is believed to address the drawing rejection. There is no new matter added.

Applicants gratefully acknowledge the allowability of claims 8, 13-16, 18 and 19, but believe that the original claims without amendment are allowable based on the following.

CLAIM REJECTIONS 35 USC § 103.

Claims 1, 2, 4-7, 9-12, 17, and 20 stand rejected under 35 U.S.C. section 103(a) as being unpatentable over Vilendrer (U.S. 5,670,708) in view of the Journal of Interventional Cardiology paper to Bier, et al. Applicants respectfully assert that the present invention as claimed is not obvious over Vilendrer in combination with Bier, et al., and further that the combination is not suggested by either reference.

Vilendrer discloses an intravascular prosthesis fatigue tester which is best seen in cross-section in Figure 6. In the description in column 2, lines 10-51, the fatigue tester utilizes a fluid conduit that includes "at least one elastic simulated arterial/venous tube which approximates the geometry of a healthy human arterial/venous vessel." The prosthesis is placed within the tube which is pressurized with a temperature controlled fluid and the radial dilation thereof is measured with a compliance transducer. In column 4, line 25, the tube is said to be made from a "flexible latex rubber."

The system disclosed in Vilendrer is manufactured by Endura-Tec Systems Corporation of Minnesota, and has been used for a number of years in the testing of such prostheses. Indeed, such systems were described in the background of present application at the bottom of column 3. The systems only utilize synthetic tubes as the conduits for testing the prostheses. There is no suggestion in Vilendrer to replace the four latex tubes in the illustrated device with anything but latex, and as mentioned in the background of the present application at page 3, line 17, such prior

art systems typically use compliant tubes of latex or silicone. One obvious reason for utilizing artificial tubes is the ability to easily control and therefore rely on the physical characteristics of the tubes.

The examiner admits that Vilendrer does not disclose an animal tissue tube, and cites the technical paper of Bier, et al. to supply such a missing element. However, the paper to Bier, et al. also does not disclose an animal tissue tube as a pressurized conduit for compliance testing. Instead, the porcine carotid or femoral arteries were merely used in a morphology study to see how well the collagenous stents under test expanded within the vessels when hydrated. That is, on page 188 under the heading "Morphology Study" the stents were folded and manually deployed into the explanted vessels, and following hydration the entire assemblies were embedded in paraffin and sectioned and stained for inspection. In separate tests to measure the effect of the implanted stents on flow, the stents were placed in tubes of "constant diameter polyvinylchloride" which were subjected to constant (i.e., non-pulsatile) perfusion pressures.

Claim 1 of the present application provides a compliance testing assembly which has an animal tissue tube and a pre-tester including fixtures sealingly coupled to the free ends of the tube and having a fluid supply in communication with the tube lumen. A stent or stent graft is positioned within the animal tissue tube which can be subjected to fluid flow for testing the compliance of the prosthesis within the tube. Vilendrer does not disclose the use of an animal tissue tube and does not suggest substituting one for the latex tube disclosed. Even in view of the technical paper to Bier, et al., one of skill in the art would not be motivated to utilize an animal tissue tube for the flow or pulsatile testing because Bier, et al. utilize PVC tubes for their flow testing. Moreover, the combination of the two references is not suggested by either. First, there is no mention of modifying the tester tubes in Vilendrer to be anything but latex. Conversely, Bier, et al. do not provide any explanation of alternative testing assemblies other than that disclosed for the morphology study and the flow study. The paper instead focuses on the construction and performance of the "new bioresorbable stent constructed of type I collagen," and, at least for flow testing, adopts the conventional system of testing the stents within an artificial (PVC) tube. In other words, there would be no motivation to combine the two references because the straightforward and conventional disclosure of testing apparatus in Bier,

et al. adds nothing to the relatively complex and sophisticated testing system disclosed by Vilendrer. Accordingly, claim 1 and its dependents 2-8 are believed allowable over the cited references.

Claim 9 provides a method of testing the compliance of a stent or stent graft including using an animal tissue tube and flowing a fluid therethrough. As stated above, Vilendrer does not disclose or suggest the use of an animal tissue tube, and the combination with Bier, et al. is insufficient and unwarranted. Accordingly, claims 9-16 are believed allowable over the cited references.

Claim 17 does not specify the use of an animal tissue tube for testing the compliance of stents or stent grafts, but instead recites the methodology of utilizing a pre-tester before a tester. The pre-tester tube is pressurized to pulsatile pressures found in the human vascular system and the exterior diameter thereof is measured and recorded. Subsequently, the stent or stent graft is placed in a tester tube and the tube pressurized at a pulsed rate at pressures controlled based on the recorded data from the pre-tester. In contrast, Vilendrer does not disclose the use of a pre-tester including a pre-tester tube, and in general does not disclose any method or means for calibrating the final tester apparatus. Instead, as stated in column 2, lines 42-51 (and later, in column 6, lines 4-54), the tester disclosed in Vilendrer utilizes a feedback loop including a transducer for measuring the tester tube's radial dilation and a microprocessor-based controller. A signal corresponding to the dilation of the tube may be used to ensure that the test is run at a specific dilation range. There is no separate pre-tester and tester, and the examiner errs in lumping the two functions together (e.g., with the use of the term "tester/pre-tester"). In claim 17, these are two separate method steps, which is clearly explained in the present application. Therefore, applicants asserted that claim 17 and appended claims 18-20 are allowable over Vilendrer in combination with Bier, et al. to

Claim 3 stands rejected under 35 U.S.C. section 103(a) as being unpatentable over Vilendrer in view of Bier, et al., and further in view of Love, et al. (U.S. 5,662,705). Applicants respectfully assert that because claim 1 is not obvious over Vilendrer in combination with Bier, et al., that the further combination with Love, et al. does not render claim 3 obvious.

In view of the foregoing remarks, Applicants assert that claim 1-20 are allowable over the cited references. If there is any further hindrance to allowance of the claims, the Examiner is encouraged to contact the undersigned by telephone.

Respectfully submitted,

Dated: April 1, 2003

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CERTIFICATE OF MAILING PURSUANT TO 37 C.F.R. § 1.10

I hereby certify that on April 1, 2003 the above-identified document (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage for "Express Mail Post Office to Addressee," Mailing Label No. EV 220642667 US, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Kathy Butterly
Kathy Butterly